



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA-2017-N-6216]

General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing this proposed order to reclassify the needle destruction device, renaming the device to “sharps needle destruction device,” a postamendments class III device (regulated under product code MTV), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. If finalized, this order will reclassify these types of devices from class III to class II and reduce regulatory burdens on industry as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: Submit either electronic or written comments on the proposed order by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN *FEDERAL REGISTER*]. Please see section XI of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions")

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-6216 for “General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher K. Dugard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2561, Silver Spring, MD 20993, 240-402-6031, christopher.dugard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and

effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 388-391 (D.D.C. 1991)) or in light of changes in “medical science” (*Upjohn v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the “new

information” to support reclassification under 513(f)(3) must be “valid scientific evidence”, as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

II. Regulatory History of the Devices

On February 3, 1994, FDA issued a Memorandum to manufacturers and initial distributors of sharps containers and destroyers used by health care manufacturers to clarify the regulatory status of sharps destroyer devices (Ref. 1).

On March 6, 1997, FDA approved its first needle destruction device through its PMA process under section 515 of the FD&C Act (21 U.S.C. 360e). In the June 11, 1997, *Federal*

Register notice (62 FR 31831), FDA announced a PMA approval order for Millenium Medical Supply's Incorporated Needle-Ease™ 2501¹ device and the availability of the Summary of Safety and Effectiveness Data for the Device (SSED) (Ref. 2). As of the date of issuance of this proposed order, FDA has approved 18 original PMAs for this device type.²

On March 2, 2001, FDA finalized guidance entitled, "Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices," describing the Agency's recommendations for information to include in PMA applications for sharps needle destruction devices intended for use in health care settings (Ref. 3).

III. Device Description

A sharps needle destruction device is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. A sharps needle destruction device is a prescription device intended for home use or in professional health care facilities to destroy sharps or needles used for medical purposes by incineration or mechanical means. Sharps needle destruction devices are typically electrical devices that can destruct sharps and/or needles in a variety of methods (grinding, incinerating, etc.) that can be either portable or stationary. Some of these devices may also employ software to provide the user with greater control. Please note these devices were originally identified as needle destruction devices (product code MTV) in FDA SSEDs and product code database; however, FDA believes the identification of sharps needle destruction device more accurately describes this device type as it can be used to destroy devices other than needles (e.g., sharps).

IV. Proposed Reclassification

¹ FDA approved a modified needle destruction device on February 11, 1998. The device, as modified, is marketed under the trade name Needle-Ease®3500.

² See PMA database for original PMAs regulated under the product code MTV:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>.

As part of the Center for Devices and Radiological Health's 2014-2015 strategic priority "Strike the Right Balance Between Premarket and Postmarket Data Collection," a retrospective review of class III devices subject to PMA was completed to determine whether or not, based on our current understanding of the technology, reclassification may be appropriate. On August 8, 2016, FDA published a document in the *Federal Register* entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection" in which FDA announced plans to reclassify sharps needle destruction devices identified with the MTV product code from class III to class II (81 FR 52445). FDA has found that sufficient information exists to establish special controls that, together with general controls, can provide a reasonable assurance of safety and effectiveness for sharps needle destruction devices.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II. FDA believes that there is sufficient information available to FDA through FDA's accumulated experience with these devices from review submissions, peer-reviewed literature, and knowledge of similar devices to establish special controls that effectively mitigate the risks to health identified in section V. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA is proposing to create a separate classification regulation for sharps needle destruction devices that will be reclassified from class III to II. Under this proposed order, if finalized, the sharps needle destruction devices will be identified as a prescription device. As such, the prescription device must satisfy prescription labeling requirements (see § 801.109 (21

CFR 801.109), *Prescription devices*). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and § 801.5 (21 CFR 801.5), as long as the conditions of § 801.109 are met. In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for sharps needle destruction devices.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary for sharps needle destruction devices to provide reasonable assurance of the safety and effectiveness. Therefore, the Agency does not intend to exempt these proposed class II devices from 510(k) requirements. Persons who intend to market this type of device must submit to FDA a 510(k) and receive clearance prior to marketing the device.

V. Risks to Health

After considering the information available to FDA through review submissions, peer-reviewed literature, and knowledge of similar devices, FDA determined the probable risks to health associated with the use of sharps needle destruction devices are as follows:

- *Patient/user exposure to environmental contaminants.* Destroying a used sharp or needle may generate hazardous emissions from the device that may result in infection or respiratory problems for the patient and/or user. Contamination of the patient environment can occur through emission of toxic fumes or infectious aerosol when the device destroys a sharp by incineration or mechanical means, and may result from

device malfunction (mechanical and/or software). The device may also become contaminated through regular usage and may cause cross-contamination.

- *Patient/user burns as a result of excessive heat discharge or spark formation.*
Excessive heat or sparks may be generated and discharged from the device during destruction of sharps that may burn the user.
- *Electromagnetic interference.* While in operation, the device may interfere with other electrically powered devices, causing them to malfunction.
- *Electrical shock.* While in operation, the device may discharge electricity that could shock the user.
- *Sharps injury.* Incompletely destroyed sharps, physical device instability, device malfunctions, or use error may pose a risk for a sharps injury to the user.

VI. Summary of Reasons for Reclassification

FDA believes that the sharps needle destruction devices intended for home use or in professional health care facilities to reduce the incidence of needlesticks by destroying sharps and/or needles in a variety of methods (grinding, incinerating, etc.) should be reclassified from class III to class II in light of new information about the effectiveness of these devices. There is sufficient information to establish special controls for sharps needle destruction devices, in addition to general controls, which can provide reasonable assurance of safety and effectiveness of the device, as general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. FDA believes that the risks to health associated with sharps needle destruction devices intended for home use or in professional health care facilities to reduce the incidence of needlesticks can be mitigated with special controls and that these mitigations will provide a reasonable assurance of its safety and effectiveness.

Based on a reconsideration of the available information and data, FDA believes that there is valid scientific evidence of effectiveness for sharps needle destruction devices to reduce the incidence of needlesticks.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Taking into account the probable health benefits of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this postamendments class III device into class II. FDA has considered and analyzed the following information: an inclusive search of the Agency's Manufacturer and User Facility Device Experience (MAUDE) database, which shows no adverse events for sharps needle destruction devices; data contained in PMAs approved 6 or more years before the date of this proposal (reviewed under section 520(h)(4) of the FD&C Act, also known as the 6-year rule); a review of sharps containers regulated under 21 CFR 880.5570, which have similar intended uses, but different technology, and are currently regulated as class II devices; and one relevant article found from a literature search that discussed the benefits and the probable risks of these devices (Ref. 4).

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in section V and provide a reasonable assurance of safety and effectiveness for sharps needle destruction devices.

- Performance testing will demonstrate:

- The device's ability to contain or ventilate aerosols or fumes from device operation that may result in environmental contamination and cross-contamination. Performance testing will demonstrate that harmful fumes, such as ozone, are not emitted by the device during destruction of sharps needles.
- Excessive heat or sparks are not generated during device operation that may injure users or patients through characterization of the heat dissipation profile from the heat source to the enclosure surface, and the point of contact between the held syringe and the user. Performance testing will ensure the heat generated through normal operation of the device will not harm users or patients or affect circuit performance and useful life of the device.
- Complete destruction of sharps intended to be destructed to mitigate user injuries from incomplete sharps destruction by conducting performance testing such as simulated use demonstrating complete destruction of the sharps and/or needles intended to be destroyed.
- Mitigation of injuries from device instability through characterization of the vibrations and movement generated by the device to ensure device stability in the use environment.
- Validation of cleaning and disinfection instructions to demonstrate that the device can be safely and effectively reprocessed after use to minimize the risk of patient/user cross-contamination.
- Performance testing ensures electromagnetic compatibility with other devices under conditions which are consistent with the intended environment of device use.

- Electrical safety testing ensures the risk of shock to the patient/user is minimized.
- Software hazard analysis, as well as software verification and validation, ensures that software performs as intended and potential software malfunctions do not impact the performance of the device.
- Labeling to ensure proper use of the device, including warnings of the generation of excessive heat, potential for needle stick injuries, instructions for reprocessing, and instructions for installation (e.g., on a stable surface, adequate ventilation).

Table 1 shows how FDA believes these special controls will mitigate each risk to health described in section V.

Table 1: Risks to Health and Mitigation Measures for Sharps Needle Destruction Devices

Identified Risk to Health	Mitigation Measures
Patient/user exposure to environmental contaminants	Performance testing Reprocessing validation Software verification, validation, and hazard analysis Labeling
Patient/user burns	Performance testing Labeling
Electrical shock	Electrical Safety Testing Labeling
Electromagnetic interference	Electromagnetic Compatibility (EMC) Testing Labeling
Sharps injury	Performance testing Software verification, validation, and hazard analysis Labeling

In addition, FDA is proposing to limit these devices to prescription use under § 801.109. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and § 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) notification requirements. FDA does not believe that clinical data is necessary to mitigate the identified risks to health for sharps needle destruction devices.

FDA may request clinical data to evaluate substantial equivalence when a manufacturer includes new indications for use, such as indications for disease prevention or organism destruction.

This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of sharps needle destruction devices. FDA intends to withdraw the final guidance entitled, "Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA" issued in 2001 upon finalization of this proposed reclassification order (Ref. 3).

IX. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520) is not required. This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

XI. Proposed Effective Date

FDA proposes that any final order based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

XII. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA memorandum “To Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals,” February 3, 1994, available at: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070679.pdf>.
2. FDA “Premarket Approval of Millenium Medical Supply Incorporated Needle-Ease™ 2501-ACTION,” March 6, 1997, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/p960044.pdf.
3. “Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA,” March 2, 2001, available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073601.pdf>.
4. Tamplin S.A., D. Davidson, B. Powis, and Z. O’Leary, “Issues and Options for the Safe Destruction and Disposal of Used Injection Materials,” *Waste Management*, vol. 25, pp. 655-665, 2005.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 880 be amended as follows:

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 880.6210 to subpart G to read as follows:

§ 880.6210 Sharps needle destruction device.

(a) *Identification.* A sharps needle destruction device is a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance testing must demonstrate the following during operation of the device:

(i) The device safely contains or ventilates aerosols or fumes from device operation.

(ii) Excessive heat or sparks are not generated that may injure users or patients.

(iii) Simulated use testing must demonstrate sharps and/or needles are completely destroyed using a range of types and sizes of sharps sufficient to represent actual use.

(iv) Simulated use testing must demonstrate that the device is physically stable on the surface for which it is intended to be mounted to ensure the risk of harm to the patient/user as a result of the device falling is minimized.

(2) Validation of cleaning and disinfection instructions must demonstrate that the device can be safely and effectively reprocessed after use per the recommended cleaning and disinfection protocol in the instructions for use.

(3) Analysis and/or testing must validate electromagnetic compatibility (EMC) and electrical safety, including the safety of any battery used in the device, under conditions which are consistent with the intended environment of device use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include:

- (i) A clear description of the device and its technological features;
- (ii) How the device is to be used, including validated cleaning and disinfection instructions;
- (iii) Relevant precautions and warnings based on performance and in-use testing to ensure proper use of the device; and
- (iv) Instructions to install device in adequately ventilated area and stable area.

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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